REMARKS

In the aforesaid Office Action, claims 1-5, 9, 16, 17, 25, 27-33, 37-45 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Estrada et al. (U.S. Patent No. 6,193,686), claims 1-5, 9, 16, 17, 25, 27-33, 37-45 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Happ et al. (U.S. Patent No. 6,575,958), claims 1-5, 9, 23-33, 35, 37-39, and 42-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Verbeek (U.S. Patent No. 5,690,613) in view of Rau et al. (U.S. Patent No. 6,024,722) and in view of Samuelson et al. (U.S. Patent No. 6,165,166), and claim 40 was objected to for informalities. Applicants note with appreciation the indication that claims 18, 19 and 21 would be allowable if rewritten in independent form including all the limitations of the base and any intervening claims. Claims 1-5, 9, 16-19, 21, 23-33, 35 and 37-46 are pending (new claim 46 being added by this amendment), and claims 6-8, 10-15, 20, 22, 34 and 36 are cancelled.

Applicants appreciate the courtesies extended by the Examiner in the telephone interview on July 28, 2004, conducted between Applicant's representative, Priscilla Morrison, and the Examiner. Applicant's summary of the interview is given below.

In the July 28, 2004 interview, Fig. 1, and claims 1, 30, 41 and 43 of Applicant's application, and Estrada et al. 6,193,686, Happ et al. 6,575,958, and Verbeek 5,690,613 in view of Rau et al. 6,024,722 and Samuelson et al. 6,165,166 were discussed. Applicants pointed out to the Examiner that there are structural differences between Estrada et al. and the embodiments set forth in Applicant's claims. Specifically,

regarding claim 1, Applicants stated that in Estrada et al., the reinforcing member 27 proximal end is on member 20, and therefore the reinforcing member 27 does not define the inner-most surface of the shaft extending along the inflation lumen from the proximal to the distal end of the reinforcing member. Applicants stated that similarly in Happ et al., reinforcing member 130 proximal end is on 94. Applicants stated that the presence of mandrel 36 does not effect the fact that the reinforcing member 27 defines the inner-most surface of the shaft extending along the inflation lumen from the proximal to the distal end of the reinforcing member because the inflation lumen is defined by a tubular member of the shaft and therefore not by the mandrel. Applicants stated that in Estrada et al. and Happ et al. a polymeric tubular member extends off the distal end of a stiff proximal tubular member, whereas the high glass transition temperature reinforcing tube in the embodiment of claim 1 defines the inflation lumen along its entire length. Applicant's agreed to amend claim 1 to clarify that the reinforcing tube, along its entire length, defines the inner-most surface of the shaft along the inflation lumen. Regarding claims 1, 30, 41 and 43, Applicants stated that the reinforcing member is on an inner surface or within the proximal polymeric tubular member which defines a proximal portion of the inflation lumen, whereas in Estrada et al., the reinforcer 27 is within the jacket 21, but the member 20, not the jacket 21, defines the inflation lumen 17. Regarding Verbeek, Applicants stated that the reinforcers 13/17 are on an outer surface of the proximal tubular member 50 and therefore are not on an inner surface or within the proximal tubular member, and that the proximal tubular member 50 is polyimide so it wouldn't have been obvious to make 13/17 on an outer surface of member 50 out of

polyimide as well. Additionally, Applicants stated that Samuelson et al. discloses minimizing the glass transition temperature of layers of multilayered tubing, whereas the newly added claim clearly sets forth the difference between the glass transition temperature of the polymeric materials in the claimed embodiment.

The Examiner rejected claims 1-5, 9, 16, 17, 25, 27-33 and 37-45 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Estrada et al. or Happ et al., stating that Estrada et al. discloses a balloon catheter shaft having.... "a reinforcing member (27) formed of a first polymeric material (PEEK) having a glass transition temperature greater than the glass transition temperature of a second polymeric material (nylon 12) forming the distal portion of the proximal tubular member, and stating that Happ et al. discloses a balloon catheter shaft having.... "a reinforcing member (130) formed of a first polymeric material (column 5, lines 49-68) having a glass transition temperature greater than the glass transition temperature of a second polymeric material (nylon 12) forming the distal portion of the proximal inner tubular member (Figures 1-19, col. 4, line 65-col. 5, line 4, and entire reference).

The Examiner states, in the Response to Arguments section of the Office Action, that the Examiner disagrees with Applicant's argument that Estrada and Happ et al. do not show the reinforcing member defining an inner-most surface of the shaft extending along the inflation lumen.

However, in Estrada et al., although member 27 does define part of an inner-most surface of the shaft extending along the inflation lumen along a portion of the length of

the member 27, it does not define, along its entire length, an inner-most surface of the shaft along the inflation lumen from the proximal to the distal end of the polymeric tubular reinforcing member, as required by the embodiment set forth in Applicant's claim 1. Instead, in Estrada et al., reinforcing member 27 has a proximal end which is located around the distal end of member 20 (i.e., the inner-most surface of the shaft along the inflation lumen at the proximal end of the reinforcing member 27 is defined by the member 20 and not by reinforcing member 27). Moreover, the tubular member 21 formed of nylon 12, in which the reinforcing member 27 is located and which therefore appears to be the member the Examiner is using as the proximal tubular member of Applicant's invention, does not define a proximal portion of the inflation lumen as required by the embodiments set forth in claims 1, 30, 37, 41, and 43. Rather, apart from reinforcing member 27, only members 20 and 31 define a proximal portion of the inflation lumen (proximal to the distal portion of the inflation lumen in the distal shaft section).

Similarly, in Happ et al., member 130 does not define, along its entire length, an inner-most surface of the shaft extending along the inflation lumen from the proximal to the distal end of the polymeric tubular reinforcing member, as required by the embodiment set forth in Applicant's claim 1. Although member 130 does define the inner-most surface of the shaft extending along the inflation lumen along a portion of the length of the member 130, the proximal end of the member 130 is mounted over the distal end of the member 94, so that the inner-most surface of the shaft along the inflation lumen at the proximal end of the reinforcing member 130 is defined by the member 94

and not by reinforcing member 27). Moreover, the tubular member 58 formed of nylon which appears to be the member the Examiner is using as the proximal tubular member of Applicant's invention, does not define a proximal portion of the inflation lumen as required by the embodiments of claims 1, 33, 37, 41, and 43. Rather, apart from reinforcing member 130, only member 94 defines a proximal portion of the inflation lumen (proximal to the distal portion of the inflation lumen in the distal shaft section). Tubular member 58 is actually the outer tubular member of the distal shaft section 19.

Regarding claim 2, Happ et al. does not disclose or suggest forming member 130 of a polyimide. Instead, Happ et al. discloses at column 5, lines 49-68, forming the member 130 of PEEK, polyetherketone, polyketone, PTFE, or nylon. Moreover, regarding claim 29, Happ et al. does not disclose or suggest that reinforcing member 130 has a wall thickness of about 0.01 to about 0.03 mm. Instead, Happ et al. disclose that the member 130 has a wall thickness of about 0.004-0.008 inches (0.1-0.2 mm), <u>an order of magnitude</u> larger than the dimensions required by claim 29. As discussed in Applicant's specification (see 3rd paragraph of the Summary section), the polyimide provides a thin-walled reinforcing tube which nonetheless has a sufficient strength to provide the required reinforcement, with excellent dimensional stability at the processing temperature of other polymers such as polyamides and polyurethanes commonly used in catheter components, and maintains thin-walled, controlled dimensions during formation and assembly of the catheter.

Additionally, Applicants wish to note that contrary to the Examiner's assertion, Happ et al. at col. 4, line 65-col. 5, line 4 does not disclose using Nylon 12 to form the distal portion of a proximal tubular member.

The Examiner rejected claims 1-5, 9, 23-33, 35, and 37-39, and 42-45 under 35 U.S.C. §103(a) as being unpatentable over Verbeek in view of Rau et al. and in view of Samuelson et al., stating that Verbeek discloses a proximal tubular member 50, a mandrel 30,.... and a reinforcing member 13, 17, but fails to disclose the reinforcing member is formed from a thermoset or thermoplastic polyimide, or the polymeric material forming the distal portion of the proximal tubular member is a nylon or polyetherblock amide, polyurethane, or adhesive polymer, or the polymeric material forming the reinforcing member has a higher glass transition temperature than the polymeric material forming the distal portion of the proximal tubular member, but Rau discloses the advantage of using a thermoset polyimide in a catheter wall because of the high strength and flexibility and Samuelson et al. discloses using different polymers with different glass transition temperatures.

However, the reinforcing members 13,17 are on an outer surface of the distal portion of the proximal tubular member 50 and therefore not on an inner surface of a portion of the proximal tubular member as required by claims 1, 41 and 43, or within the distal portion of the proximal tubular member as required by claim 30, or within the inner tubular member or the proximal tubular member as required by claim 37. Similarly, Samuelson et al. discloses that the <u>inner</u> layer has the <u>lowest</u> glass transition temperature, in contrast to the embodiments set forth in Applicant's claims 1, 30, 41, and 43 calling

for the reinforcing member having a higher glass transition temperature on an inner surface or within a portion of the proximal tubular member.

Additionally, regarding claim 45, in Verbeek, the proximal tubular member 50 is formed of polyimide. Although Rau does disclose the use of thermoset and thermoplastic polyimides for a high strength thin walled member, because the reinforcing members 13, 17 of Verbeek are on polyimide tubing 50, it would not have been obvious to one of skill in the art at the time the invention was made to modify Verbeek in view of Rau to form the reinforcing members 13,17 also from polyimide (the resulting catheter having reinforcement polyimide tubing 13,17 on polyimide tubing 50). Additionally, although Samuelson discloses using different polymers with different glass transition temperatures, Samuelson discloses that the layers of the multilayered tube are preferably comprised of materials with glass transition temperatures that are substantially similar so as to facilitate coextrusion and to help reduce the tendency of undue stress to build between the layers in the resultant tubing. In contrast, the reinforcing tubular members 13, 17 of Verbeek are not coextensive or coextruded with the polyimide tube 50. Thus, the combination of the references does not disclose or suggest modifying the nature of the polymers forming the reinforcing tubular member 13,17 and polyimide tube 50 in such a way as to disclose the embodiments of Applicant's catheter as claimed. In the embodiments of Applicant's catheter set forth in the claims, a reinforcing tubular member within a portion of the shaft has a higher glass transition temperature than the shaft portion, and, contrary to the Examiner's assertion, the combination of Verbeek in view of Rau and Samuelson et al. does not disclose forming the reinforcing member 13, 17 from a thermoset or

thermoplastic polyimide, and the combined references do not disclose or suggest a catheter in which the first polymeric material forming the reinforcing member has a higher glass transition temperature than the second polymeric material forming the distal portion of the proximal tubular member. Moreover, new claim 46 sets forth specific glass transition temperatures for the polymeric materials.

In light of the above amendments and remarks, applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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